K954124

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SECTION 11 SUMMARY of SAFETY AND EFFECTIVENESS

I. General Information:

A. Generic (USAN) Name: sterafocon A

B. Device Trade Name: O->PERM 30A

C. Sponsor's Name and Address:

Dr. Paul Schuman
Optical Polymer Research, Inc.
5921 N.E. 38th Street
Gainesville, FL 32609
(904) 378-1027

D. 510(k) Number: K954124

E. Date Notice of approval sent to Sponsor:

F. First OPR Approved Alternate Site Manufacturer and Distributor of Lenses made from the O->PERM 30 A (sterafocon A) optical blanks (Pending FDA approval):

Salvatori Ophthalmics Mfg. Inc.
6416 Parkland Drive
Sarasota, FL 34243
(813) 751-0383

II. Indications

RGP Spherical contact lenses made from O->PERM 30A (sterafocon A) which contain a visibility tint are indicated for daily wear use. The lenses are indicated for visual acuity in patients with with non-diseased eyes. The spherical lenses are being applied for from +12.00 to -20.00 Diopters up to 4.00 Diopters of astigmatism where it does not interfere with visual acuity.

RGP Toric contact lenses made from O->PERM 30A (sterafocon A) which contain a visibility tint are also indicated for daily wear. The lenses are indicated for visual acuity in patients with with non-diseased eyes. The toric lenses are being applied for from +12.00 to -20.00 Diopters up to 6.00 Diopters of astigmatism where it does not interfere with visual acuity.

III. Device Description

O->PERM 30A (sterafocon A) is a RGP silicone-acrylate polymer which can be lathed into spherical or toric contact lenses. These hemispherical shells when placed on the eye

act as a refracting medium to focus light rays on the retina.

IV. Alternative Practices or Procedures

Alternative practices or procedures are the use of other available previously approved RGP silicone-acrylate contact lenses or soft (hydrophilic) contact lenses or prescription spectacles as deemed best by the patient's eye care practitioner.

V. Technical Summaries

A. Nonclinical

1. Toxicology

Optical Polymer Research, Inc. had all the pre-clinical testing studies necessary for IRB review for Class II daily wear RGP contact lenses. The South West Independent IRB granted their approval to OPR's protocol to start a clinical study on O->PERM 30 A (sterafocon A) for daily wear on June 6, 1994.

Conclusion: Approved by IRB

2. Microbiology

To assure that a low bioburden level is maintained by alternate site lens manufacturers, a yearly bioburden test will be done using a validated bioburden test method. A <100 CFU/lens will be the specification for bioburden. Implementation of written quality assurance measures will be assured by all alternate sites.

Conclusion: Approved by IRB

3. Lens compatibility studies: Used FDA approved RGP contact lenses solutions. Some preliminary bench work to assure compatibility.

Conclusion: Approved by IRB

4. Lens Stability: not required with the RGP material.

5. Preservative Uptake Tests: Are not required with the RGP material.

B. Clinical

This study was run with the help of Salvatori Ophthalmics Manufacturing Inc. of Sarasota, Florida. The clinical study started after obtaining IRB approval.

Optical Polymer Research, Inc. (OPR) will own the material O->PERM 30A (sterafocon A) and has submitted a protocol for the acceptance of alternate site finishing labs. All labs will be subject to testing

and, if they pass, acceptance.

The equipment manufacturers of lathes and polishing equipment may be different between the various contact lens labs but the finished product will be equivalent in all instances. The recommended manufacturing materials, manufacturing methods, and quality control methods employed by the companies are specified by OPR.

Optical Polymer Research, Inc. was last FDA inspected on August 15/17, 1995

C. Patient Selection:

Each patient was be selected according to the following criteria:

1. They must fill in and sign an informed consent form (as approved by the IRB) before any trial lens is dispensed. There are to be no exceptions. .
2. Have no excessive corneal astigmatism that would interfere with the correction of visual acuity.
3. The patients eyes should be correctable to at least 20/30 for distance as a minimum standard.
4. They must have non-diseased eyes which are normal or which have a preexisting ocular condition which would not be expected to interfere with the patient's ability to wear contact lenses successfully. A normal eye is defined as one having all the following characteristics:

    a. No evidence of lid infection.
    b. No structural lid abnormality
    c. No conjunctival abnormality or infection
    d. A cornea which is clear with no edema, staining, vascularization or abnormal opacities, all as observed by slit lamp examination.
    e. No iritis.
    f. No other active disease that would contraindicate the wearing of contact lenses or has caused the patient to terminate contact lenses at some previous time.

5. Use no ocular medication.

6. Have no known sensitivity to solutions currently used by the investigator for lens care.

7. Have binocular correction with contact lenses.

The Food and Drug Administration is aware that certain patient characteristics such as mild edema or staining or other minor physical conditions may not necessarily preclude the patient from participating in the study: however, these conditions should be well documented in the preliminary or initial visit and followed during the study.

D. Study Period

The study period was defined as three (3) months continuous wear. The patients were seen by the Investigators at 7 days, 14 days, 1 month, 2 months and 3 months following the initial dispense date.

E. Study Population

The study population was to consist of randomly selected patients, approximately fifteen (15) per investigator with a random distribution of 2:1 in the trial lens : control lens.

1. Safety appears to be well within Normal Limits

The safety of the O->PERM 30 A polymer (sterafocon A) is demonstrated by the study to be well within normal limits for a contact lens of this class.

a. Adverse Reactions

There were no lens related Adverse Reactions reported in the study.

b. Slit Lamp Findings

All Slit Lamp Findings were typical of that which is generally expected from patients wearing contact lenses in this class. No slit lamp findings required treatment.

2. Effectiveness

The effectiveness of the O->PERM 30 A (sterafocon A) is demonstrated by the study to be well within Normal Limits for a contact lens in this class.

a. Visual Acuity

The majority of the patients completing the study period exhibited a final VA of 20/30 or better: 68 eyes out of 72 (94.4%) for the trial lens and 30 eyes out of 34 (88.2%) for the control lens.

b. Wearing Time

The average wearing time for all patients participating in the Study was typical of daily wear patients generally: 10 to 14 hours per day.

c. Discontinued Patients

Patient discontinuations were normal for contact lens patients in general with 6 out of 36 (16.7%)

in the trial cell, and 3 out of 17 (17.6%) in the control cell.

d. Symptoms Problems and Complaints

There were no unanticipated observations in this category and none of the observations noted required treatment or gave any cause for a determination of a problem directly attributable to the wearing of the trial lenses.

e. Replacements

Lens replacements during the study were mostly for fitting related reasons, or other normal contact lens wearing related reasons (such as loss).

I. Potential Adverse Effects of the Device on Health

None known

II. Conclusion drawn from Study

It can be concluded from the clinical study results that the O->PERM 30 A (sterafocon A) polymer is Safe and Effective for daily wear use in patients with non diseased eyes.

III. FDA Recommendation

It is recommended that the FDA approve the O->PERM 30 A (sterafocon A) for Daily wear use.